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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,489	03/08/2002	Barbara L. Merboth	X-9353	1281

7590 05/15/2003

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EXAMINER

FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 05/15/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/092,489

Applicant(s)
Merboth et al.

Examiner
Jimmy G. Foster

Art Unit
3728



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 and 25-32 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 14, 15, 19, and 22 is/are rejected.
- 7) ☒ Claim(s) 5, 8-13, 20, 21, 23, and 24 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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1. Claims 16-18 and 25-32 are allowable. Regarding claim 32, while the insert 16 of Bowman et al includes a groove, e.g. 21, with a single stepped end, the groove does not include more than one stepped end.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Krueger (5,868,253). While the packaging of Krueger is for a heart valve and not for a tissue implant form, Applicant is not positively reciting the tissue implant form in the claims as structure but as intended use.

The packaging of Krueger et al includes an outer container at 18, and inner container at 20, an insert member at 22, a permeable cover at 24, and an outer cover at 26. The permeable cover 24 is sealed to the flange 32 of the inner container. The flange 32 of the inner container fits into the stepped recess/shoulder 36 of the outer container. The outer cover is sealed to the flange 34 of the outer container. The insert 22 is sized to fit into the inner container 20. The permeable cover includes a tab to be pulled/grasped for opening the cover.

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The insert 22 is intended for retaining the combination of a valve holder 14 and a heart valve 16. However, the insert is capable of retaining instead a human tissue graft implant form of appropriate size and shape because the clamp/shaped structure 86 of the insert is capable of holding a tissue graft implant form of appropriate size and shape. Inasmuch as Applicant does not recite the implant form as structure in the claims, this capability of the insert 22 of the reference is asserted by the examiner to meet what Applicant has claimed regarding the holding a tissue implant form. The shaped structure/clamp 86 is considered to define a groove.

Regarding Applicant's claim 7, the shaped structure is one portion of the claim 86, including the semi-circular groove and the stepped end portions 88A.

4. Claim 22 is rejected under 35 U.S.C. § 102(b) as being anticipated by Bowman et al (4,736,850). Bowman et al discloses an outer container/tray at 12, and inner container tray, and insert 31, an inner cover 17 and an outer cover 13. The insert is capable of holding a human graft tissue implant form, such as in the vein holding groove/depression 30 thereof, this capability meeting the intended use claimed by Applicant regarding the holding an implant form.

The combination of the groove 30 and one of the elements 32 at the end of the groove is considered to define a stepped arcuate groove.

The inner container and outer container both have side and end walls angularly oriented with respect to the bottom. The

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insert 31 includes a base flange, which the examiner asserts reads upon Applicants claimed tab.

5. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6, 7, 14, 15 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bowman et al (4,736,850) in view of Krueger et al (5,868,253). Bowman et al discloses an outer container/tray at 12, and inner container tray, and insert 31, an inner cover 17 and an outer cover 13. The insert is capable of holding a human graft tissue implant form, such as in the vein holding groove/depression 30, this capability meeting the intended use claimed by Applicant regarding the holding an implant form.

Elements 32 define notched recesses. The combination of the groove 30 and one of the elements 32 is considered to define a stepped arcuate groove.

The inner container and outer container both have side and end walls angularly oriented with respect to the bottom. The insert 31 includes a base flange, which the examiner asserts reads upon Applicants claimed tab or tab member of claims 3 and 19.

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Although the reference of Bowman et al does not disclose permeable covers, the reference of Krueger et al at 24 and 26 suggests that medical containers may be provided with permeable covers for the purpose of permitting steam or gas sterilization of the contents. Accordingly for this reason it would have been obvious in view of Krueger et al to have made the covers 13 and 17 of Bowman et al permeable.

7. Claims 5, 8-13, 20, 21, 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 5 is objected to as redundantly calling for the permeable/inner container cover to be permeable. (The "outer container cover" is considered to refer to the outer cover of claim 1, and the inner container cover is considered to refer to the permeable cover of claim 1.) Claim 5 would be allowable if it is amended to be made independent so as to include further all of the limitations of claim 1 while removing the redundancy.

8. For contacting the PTO by phone, the following contact numbers may be used:

For tracking of papers and association of papers with cases --
Customer Service. . . (703)306-5648

For matters regarding examination -- Examiner:
Jim Foster (703)308-1505

For faxing of correspondence:
DRAFT Fax amendments only-(703)308-7769
(Examiner should be notified of fax)

FORMAL Regular Fax correspondence-(703)305-3579 or 305-3580

FORMAL RIGHT FAX- Before Final . . (703) 872-9302
After Final . . . (703) 872-9303

Serial Number: 10/092,489

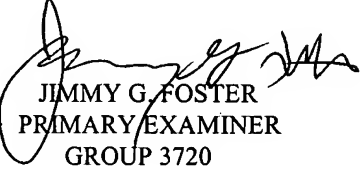
-6-

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(The examiner ordinarily will not retrieve
formal correspondence)

For petitions:

Before the Examiner . (703)308-1505
Before the Group Director . (703)308-3872
Other petitions . . . (703)305-9282


JIMMY G. FOSTER
PRIMARY EXAMINER
GROUP 3720

JGF
May 12, 2003